HepaSphere™ MICROSPHERES

ENGLISH

INTENDED USE
HepaSphere™ Microspheres are indicated for use in embolization of blood vessels for therapeutic or preoperative purposes in the following procedures:
- Embolization of hepatocellular carcinoma
- Embolization of metastases to the liver

DESCRIPTION
HepaSphere Microspheres are part of a family of embolic agents based on proprietary technologies. They are designed for controlled, targeted embolization. HepaSphere Microspheres are biocompatible, hydrophilic, non-resorbable, expandable, and conformable microspheres. HepaSphere Microspheres swell upon exposure to aqueous solutions. They are available in a range of sizes.

Dry (µm)
50-100
30-60
20-40

DEVICE PACKAGING
HepaSphere Microspheres are contained in a sterile, 10 ml Cyclo Olefin Polymer (COP) vial, with a crimped cap, packaged in a sealed pouch.
Contents: 15 mg, 25 mg or 50 mg of dry HepaSphere Microspheres per vial to be reconstituted in NaCl 0.9% aqueous solution before use (or aqueous solution of equivalent ionic concentration).

CONTRAINDICATIONS
- Patients intolerant to vascular occlusion procedures
- Vascular anatomy or blood flow precluding correct catheter placement or embolic injection
- Presence or suspicion of vasospasm
- Presence or likely onset of haemorrhage
- Presence of severe atheromatous disease
- Feeding arteries too small to accept the selected HepaSphere Microspheres
- Presence of collateral vessel pathways potentially endangering normal territories during embolization
- High flow arteriovenous shunts or fistulae with luminal diameter greater than the selected size of HepaSphere Microspheres
- Vascular resistance peripheral to the feeding arteries precluding passage of HepaSphere Microspheres into the lesion
- Presence of arteries supplying the lesion not large enough to accept HepaSphere Microspheres
- Do not use in pulmonary vasculature, coronary and central nervous system vasculature
- Known sensitivity to poly vinyl alcohol-co-sodium acrylate

WARNINGS
- HepaSphere Microspheres size must be chosen after consideration of the arteriovenous angiographic appearance. HepaSphere Microspheres size should be selected to prevent passage from any artery to vein.
- Some of the HepaSphere Microspheres may be slightly outside of the range, so the physician should be sure to carefully select the size of HepaSphere Microspheres according to the size of the target vessels at the desired level of occlusion in the vasculature and after consideration of the arteriovenous angiographic appearance.
- Because of the significant complications of misembolization, extreme caution should be used for any procedures involving the extracranial circulation encompassing the head and neck, and the physician should carefully weigh the potential benefits of using embolization against the risks and potential complications of the procedure. These complications can include blindness, hearing loss, loss of smell, paralysis, and death.
- Serious radiation induced skin injury may occur to the patient due to long periods of fluoroscopic exposure, large patient, angled x-ray projections and multiple image recording runs or radiographs. Refer to your facility's clinical protocol to ensure the proper radiation dose is applied for each specific type of procedure performed.
- Onset of radiation injury to the patient may be delayed. Patients should be counselled on potential radiation effects, what to look for and whom to contact if symptoms occur.
- HepaSphere Microspheres MUST NOT be reconstituted in sterile water for injection. Reconstitution in sterile water results in extensive swelling that renders the injection of HepaSphere Microspheres very difficult or may prevent injection.
- Do not reconstitute HepaSphere Microspheres with Lipiodol / Ethiodol.
- Pay careful attention for signs of mistargeted embolization. During injection carefully monitor patient vital signs to include SaO2 (e.g. hypoxia, CNS changes). Consider terminating the procedure, investigating for possible shunting, or increasing Microspheres size if any signs of mistargeting occur or patient symptoms develop.
- Consider upsizing the Microspheres if angiographic evidence of embolization does not quickly appear evident during injection of the Microspheres.

Warnings about use of small microspheres
- Careful consideration should be given whenever use is contemplated of embolic agents that are smaller in diameter than the resolution capability of your imaging equipment. The presence of arteriovenous anastomoses, branch vessels leading away from the target area or emergent vessels not evident prior to embolization can lead to mistargeted embolization and severe complications.
- Microspheres smaller than 100 microns will generally migrate distal to anastomotic feeders and therefore are more likely to terminate circulation to distal tissue. Greater potential of ischemic injury results from use of smaller microspheres and consideration must be given to the consequence of this injury prior to embolization. The potential consequences include swelling, necrosis, paralysis, abscess and/or stronger post-embolization syndrome.
- Post embolization swelling may result in ischemia to tissue adjacent to target area. Care must be given to avoid ischemia of intolerant, non targeted tissue such as nervous tissue.

PRECAUTIONS:
HepaSphere Microspheres must only be used by physicians trained in vascular embolization procedures. The size and quantity of microspheres must be carefully selected according to the lesion to be treated and the potential presence of shunts. Only the physician can decide the most appropriate time to stop the injection of HepaSphere Microspheres.

Do not use if the vial, cap, or pouch appear damaged.
For single patient use only - Contents supplied sterile - Never reuse, reprocess, or resterilize the contents of a vial that has been opened. Reusing, reprocessing or resterilizing may compromise the structural integrity of the device and or lead to device failure, which in turn may result in patient injury, illness or death. Reusing, reprocessing or resterilizing may also create a risk of contamination of the device and or cause patient infection or cross infection including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. All procedures must be performed according to accepted aseptic technique.

HepaSphere Microspheres MUST NOT be used in their original dry state. They must be reconstituted before use. HepaSphere Microspheres swell in aqueous solution. The magnitude of swelling depends on the ionic concentration of the solution. The microspheres swell to approximately four times their diameter in 0.9% NaCl aqueous solution and non-ionic contrast media, as compared to their initial dry diameter. HepaSphere Microspheres are compressible and can be injected easily through microcatheters. However, injection of the HepaSphere Microspheres before they are fully expanded could result in failure to reach the intended embolization target and possible embolization of a larger tissue area.

Patients with known allergies to non-ionic contrast media may require corticosteroids prior to embolization.
Additional evaluations or precautions may be necessary in managing periprocedural care for patients with the following conditions:
- Bleeding diathesis or hypercoagulative state
- Immunocompromise

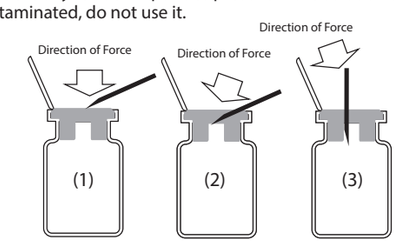
POTENTIAL COMPLICATIONS:
Vascular embolization is a high-risk procedure. Complications may occur at any time during or after the procedure, and may include, but are not limited to, the following:
- Paralysis resulting from untargeted embolization or ischemic injury from adjacent tissue oedema
- Undesirable reflux or passage of HepaSphere Microspheres into normal arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds, such as the internal carotid artery, pulmonary, or coronary circulation
- Pulmonary embolism due to arteriovenous shunting
- Ischemia at an undesired location, including ischemic stroke, ischemic infarction (including myocardial infarction), and tissue necrosis
- Capillary bed occlusion and tissue damage
- Vasospasm
- Recanalisation
- Blindness, hearing loss, and loss of smell
- Foreign body reactions necessitating medical intervention
- Infection necessitating medical intervention
- Complications related to catheterization (e.g. haematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgement, and nerve and/or circulatory injuries which may result in leg injury)
- Allergic reaction to medications (e.g. analgesics)
- Allergic reaction to non-ionic contrast media or embolic material
- Vessel or lesion rupture and haemorrhage
- Death
- Additional information is found in the Warnings section

SWELLING BEHAVIOR:
HepaSphere Microspheres swell during reconstitution with NaCl 0.9% aqueous solution and non-ionic contrast media. When hydrated in 100% NaCl 0.9% aqueous solution or non-ionic contrast medium, or 50% non-ionic contrast and 50% NaCl 0.9% aqueous solution, HepaSphere Microspheres swell approximately 4 times their original dry diameter in approximately 10 minutes. For example, HepaSphere Microspheres with a diameter of approximately 50-100 microns in their dry state will expand to approximately 200-400 microns during reconstitution as recommended below. Because of the inherent variability of the swelling process, some of the HepaSphere Microspheres will be slightly outside of this range after reconstitution, so the physician should be sure to carefully select the size of HepaSphere Microspheres according to the size of the target vessels at the desired level of occlusion in the vasculature and the nature of the aqueous solution.

CATHETER COMPATIBILITY:
HepaSphere Microspheres can be injected with microcatheters with the following specifications:

Dry (µm)	Approximate Reconstituted Size range (µm)	Catheter Size ID (in.)
20-40	80-160	≥0.020
30-60	120-240	≥0.021
50-100	200-400	≥0.021

INSTRUCTIONS:
HepaSphere Microspheres must be reconstituted with 100% NaCl 0.9% aqueous solution or non-ionic contrast medium, or 50% non-ionic contrast medium and 50% NaCl 0.9% aqueous solution before positioning the catheter.
- Carefully select the size of HepaSphere Microspheres according to the size of the target vessels at the desired level of occlusion in the vasculature and the nature of the aqueous solution. See the description of "SWELLING BEHAVIOR".
- HepaSphere Microspheres may be present outside the vial. Therefore, the vial must be aseptically handled away from the main sterile field.
- Ensure the compatibility of the HepaSphere Microspheres with the intended size of catheter to be used. See the table above.
- Inspect the packaging to confirm that it is intact. Remove the vial from the pouch. The external surface of the vial is sterile.
- To prevent coring the rubber stopper, insert the injection needle as follows:
  1. Hold the needle so that the cutting edge faces upwards and position the tip diagonally to the insertion site. Press the tip against the center of the insertion site.
  2. Apply a gentle force to the needle in the opposite direction to the cutting edge to ease the needle into the insertion site until the heel section of the needle is no longer visible. Be careful not to scrape off the upper-facing surface of the rubber cap with the heel of the needle tip.
  3. Continuing to apply a gentle force to the needle in the opposite direction to the cutting edge, slowly insert the needle vertically through the rubber cap.
  4. After preparation, carefully examine the solution to determine if there are any rubber impurities present. If the solution appears contaminated, do not use it.



PREPARATION FOR EMBOLIZATION
The approximate reconstitution time is 10 minutes.

- Fill a 10ml syringe with 100% NaCl 0.9% aqueous solution or non-ionic contrast medium (or 50% NaCl 0.9% aqueous solution and 50% contrast). Connect the syringe to a needle of 20 gauge diameter or larger.
- To ensure proper reconstitution of the HepaSphere Microspheres, grasp the vial horizontally in your fingertips and roll the vial several times. This will transfer the dry contents of the vial to the sidewall.

Note: Pull back only the flip-top cap; do not remove the crimp ring or the stopper from the vial.
- Carefully insert the needle from the syringe through the stopper of the vial. Continue rolling the vial in your fingertips and inject the full amount **(10ml)** of reconstitution medium into the vial, then place the vial vertically and carefully remove the syringe with the needle attached.

Note: The vial is hermetically closed. If aspiration from the syringe into the vial does not automatically occur, then, using caution, manually aspirate air from the vial into the syringe prior to injecting the reconstitution fluid. Proper aspiration and/or venting techniques, as approved by the healthcare facility, may be used for easier injection of reconstitution medium into vial. If aspiration of air from the vial is performed prior to reconstitution, exercise caution not to remove the spheres from the vial.
- To ensure a homogeneous reconstitution of the HepaSphere Microspheres, shake the vial back and forth so that the liquid contacts the stopper 5-10 times.
- Wait a minimum of **10 minutes** to allow the HepaSphere Microspheres to reconstitute and expand fully.
- Use a 30ml syringe and 20 gauge or larger needle to aspirate the contents of the vial. Rotate the vial to a vertical position with the bottom of the vial facing upward. Pull the needle back so that it is submerged in the liquid but not occluded by the stopper. Aspirate the entire contents of the vial into the syringe.

Note: If the air was previously aspirated from the vial, gentle injection of air using the syringe prior to aspirating the contents of the vial will ensure an easier aspiration of vial contents into the syringe. If all contents are not withdrawn, introduce an additional volume of air and repeat the aspiration process. It is possible to add an additional amount of non-ionic contrast or NaCl 0.9% aqueous solution into the syringe in order to get a higher dispersion of microspheres.
- If microspheres were reconstituted using 100% NaCl 0.9%, non-ionic contrast medium must be added to the syringe containing the HepaSphere Microspheres for visualization under fluoroscopy. If non-ionic contrast medium was used to reconstitute the microspheres, additional non-ionic contrast medium may be added.

DELIVERY INSTRUCTIONS:
- Carefully evaluate the vascular network associated with the target lesion utilizing high resolution imaging.

Note: It is important to determine if any arteriovenous shunts are present before beginning embolization.
- Using standard techniques, position the delivery catheter within the target vessel and the catheter tip as close as possible to the embolization target.
- Use an injection syringe no larger than 3ml for the delivery of HepaSphere Microspheres. Use of a 1ml injection syringe is recommended.
- Aspirate the HepaSphere Microspheres mixture into the injection syringe.
- Two methods for embolic aliquot sequestering for injection may be used:
  Option 1: Connect a 3-way stopcock to the 30ml syringe containing the HepaSphere Microspheres to the infusion micro- catheter and use a 1ml syringe for injection through the open port of the 3-way stopcock.
  Option 2: Serial aliquots of the HepaSphere Microspheres can be drawn from the 30ml syringe into a 1ml injection syringe through a 3-way stop cock that is not attached to the infusion catheter. The 1ml syringe containing each aliquot can be attached independently to the infusion microcatheter and injected.
- Shake the 30ml syringe back and forth to maintain the homogenous suspension of the HepaSphere Microspheres mixture.
- Under continuous fluoroscopic guidance, inject the aliquot of HepaSphere Microspheres in a slow, non forceful, pulsatile manner over a time period of approximately 1 minute per ml of microspheres solution. Always inject under free-flow conditions and monitor for reflux.

Note: Reflux of embolic spheres can induce immediate ischemia of untargeted tissues and vessels.
- When stasis in the feeding pedicle occurs while delivering the HepaSphere Microspheres, wait a minimum of 5 minutes then perform a selective angiogram after the full 5 minutes wait to verify the cessation of antegrade flow.
- If cessation of antegrade flow has not occurred, continue infusion under fluoroscopic guidance until the desired devascularization is obtained.
- After the HepaSphere Microsphere infusion is completed, remove the catheter while maintaining gentle aspiration to avoid dislodging any residual HepaSphere Microspheres that may still be in the catheter lumen. Discard the catheter after removal and do not reuse.
- Discard any open vial or unused HepaSphere Microspheres.

CAUTION:
In the event that the catheter becomes obstructed or significant infusion resistance is encountered during injection, do not attempt to flush the catheter with excessive pressure because reflux of embolic material may occur resulting in untargeted embolization. Remove the catheter while applying gentle aspiration and discard.

CONSERVATION AND STORAGE:
HepaSphere Microspheres must be stored in a dry, dark place in their original vials and packaging. Use by the date indicated on the labeling. When the procedure of reconstitution is completed, store the solution of HepaSphere Microspheres in 2 to 8°C conditions and use within 24 hours, IF not used immediately. Do not store HepaSphere Microspheres after contrast medium has been added.

Size of dry products (µm)	Colour code (label borders)	Quantity of microspheres (mg)	Reference
20-40	Grey	15 25 50	V 115 HS V 125 HS V 150 HS
30-60	Orange	15 25 50	V 215 HS V 225 HS V 250 HS
50-100	Yellow	15 25	V 315 HS V 325 HS

All serious or life threatening adverse events or deaths associated with use of HepaSphere Microspheres should be reported to the device manufacturer.

INFORMATION ON PACKAGING:

Symbol	Designation
	Use by date: year-month
LOT	Batch code
REF	Catalogue number
	Do not resterilize
	Do not use if package is damaged
	Keep away from sunlight
	Keep dry
	Do not re-use
	Caution - Refer to Instructions For Use
	Non-pyrogenic
STERILE R	Sterilized using irradiation
•/●	Size of dry microspheres / Size of hydrated microspheres

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HepaSphere™ MICROSPHERES 中文

栓塞微球

适用范围

栓塞微球适用于栓塞血管，并用于下列手术中以治疗或外科手术前的辅助治疗为目的的血管栓塞：原发性肝癌栓塞术 和肝转移癌栓塞术

产品描述

HepaSphere 栓塞微球属于以专有技术为基础的栓塞剂系列，旨在进行可控的靶向栓塞。HepaSphere 栓塞微球具有良好的生物相容性、亲水性、不可吸收性、可膨胀性、可变形性，暴露于水溶液即膨胀。尺寸多样，可供选择。

干燥状态下微球直径 (μm)
50-100
30-60
20-40

包装

HepaSphere 栓塞微球采用10ml环烯烃聚合物（COP）无菌铝盖瓶灌装后，以密封袋包装。每瓶含干燥栓塞微球15mg, 25mg或50mg，使用前用0.9%的生理盐水（或离子浓度相当的水溶液）进行重建。

禁忌症

- 患者对血管栓塞手术不耐受
- 血管解剖结构或血流妨碍正确置管或栓塞剂注射
- 血管痉挛或疑似血管痉挛
- 出血或可能发生出血
- 严重动脉粥样硬化疾病
- 供血动脉太细，无法接受选定的HepaSphere栓塞微球
- 侧支血管通路，栓塞过程中可能会影响正常区域
- 高流量动静脉分流或动静脉瘘，其直径大于选定的HepaSphere栓塞微球尺寸
- 供血动脉外周血管阻力妨碍HepaSphere栓塞微球进入病变部位
- 病变供血动脉不够粗，无法接受HepaSphere栓塞微球
- 不可用于肺血管、冠状动脉血管和中枢神经系统血管
- 已知对聚乙烯醇-丙烯酸钠共聚物过敏

警告

- 选择HepaSphere 栓塞微球时，必须考虑动静脉血管造影表现。选定的栓塞微球大小应该能够防止其从动脉进入静脉。
- 有些栓塞微球可能会略超范围，因此医生一定要在考虑预期血管栓塞水平以及考虑动静脉造影表现的基础上，根据靶血管的大小慎重选择栓塞微球尺寸。
- 由于异位栓塞可引起严重并发症，在涉及头颈部颅外循环的手术中应多加小心，同时医生应当仔细权衡使用栓塞的潜在好处及其风险和潜在并发症。这些并发症包括失明、失聪、嗅觉失灵、瘫痪和死亡。
- 长时间的荧光透视检查、大体型患者、角度X射线投照以及多重图像录制或X线照片会产生严重的辐射，可能引起患者皮肤损伤。查阅您所在机构的临床方案，确保每次手术所用的辐射剂量适当。
- 患者的辐射损伤可能会延迟发作。应告知患者潜在的辐射影响，确保一旦出现症状患者能够向相关人员寻求帮助。
- 不可用灭菌注射用水重建HepaSphere栓塞微球，否则会导致过度膨胀，使栓塞微球注射变得相当困难，甚至无法注射。
- 勿用碘化油/乙碘油重建HepaSphere栓塞微球。
- 要特别留心非靶组织栓塞迹象。注射过程中，仔细监测患者包括血氧饱和度（如缺氧、中枢神经系统变化）在内的生命体征。如发现非靶组织栓塞迹象或患者出现症状，则考虑终止注射，检查可能存在的分流，或者增加栓塞微球尺寸。
- 在栓塞微球注射过程中，如果血管造影并未迅速出现栓塞的征象，则考虑选用更大粒径的栓塞微球。

小粒径栓塞微球使用警告

- 使用直径小于造影设备分辨率的栓塞剂时，应考虑周详。动静脉吻合、分支血管远离靶区或栓塞前血管不明显都有可能造成靶外栓塞和严重并发症。
- 小于100微米的栓塞微球通常会从远端转移至吻合供血动脉，更有可能终止远端组织的循环。 使用小粒径栓塞微球更易造成潜在缺血性损伤，栓塞前必须考虑这种损伤可能造成的后果，包括肿胀、坏死、瘫痪、脓肿及/或较严重的栓塞后综合征。
- 栓塞后肿胀可能会导致靶区附近的组织缺血。必须多加小心，以免不耐受的非靶组织缺血，如神经组织。

注意事项

HepaSphere 栓塞微球仅限在血管栓塞术方面受过培训的医生使用。必须根据待治疗的病变以及可能存在的分流对微球的尺寸和数量进行严格挑选。停止栓塞微球注射的最恰当时机，只能由医生决定。

药瓶、瓶盖或密封袋有破损时，请勿使用。仅可用于一名患者：所提供的内容物已灭菌。开盖后，请勿重复使用、回收利用或重新消毒，否则可能会影响装置的结构完整性，或导致其出现故障，使患者受伤、生病或死亡。重复使用、回收利用或重新消毒还有可能产生装置污染风险，或导致患者感染或交叉感染，包括但不仅限于传染病在患者之间传播。设备污染可能导致患者受伤、生病或死亡。所有手术必须按照公认的无菌操作施行。

不可以在原始干燥状态使用HepaSphere栓塞微球，必须用水溶液使其膨胀，膨胀程度取决于水溶液的离子浓度。微球在0.9%的生理盐水和非离子型造影剂中膨胀后，直径几近达到干燥状态下的4倍。栓塞微球具有可压缩性，可通过微导管轻松注射。但在其充分膨胀前注射栓塞微球，可能无法达到预期的栓塞目标，并可能造成较大组织区域的栓塞。

已知对非离子型造影剂过敏的患者栓塞前可能需要服用皮质类固醇。

下列疾病患者的围手术期护理管理过程中，可能需要进行其它评估或采取其它防范措施。

- 出血性素质或高凝状态
- 免疫力低下

潜在并发症

血管栓塞术是一项高危手术，术中术后随时可能出现并发症，包括但不仅限于下列并发症：

- 非靶组织栓塞引起的麻痹或瘫痪，或邻近组织水肿引起的缺血性损伤
- HepaSphere栓塞微球发生返流，或进入靶病变附近的正常动脉，或通过病变进入其它动脉或动脉床，如颈内动脉、肺动脉或冠状动脉循环
- 动静脉分流引起的肺栓塞
- 非预期部位缺血，包括缺血性中风、缺血性梗死（包括心肌梗死）和组织坏死
- 毛细血管床闭塞和组织损伤
- 血管痉挛
- 再通
- 失明、失聪及嗅觉失灵
- 需医疗干预的异物反应
- 需医疗干预的感染
- 置管相关并发症（如插入部位血肿、导管头端血凝块形成及随之产生的导管易位、神经及/或循环受损导致的腿部损伤）
- 药物过敏反应（如镇痛药）
- 非离子型造影剂或栓塞材料过敏反应
- 血管或病变破裂和出血
- 死亡
- “警告”一节中所述的其它内容

膨胀性

栓塞微球在使用0.9%生理盐水或非离子型造影剂重建过程中膨胀。在0.9%生理盐水、或非离子型造影剂、或50%的0.9%生理盐水和50%的非离子型造影剂的混合溶液中，HepaSphere栓塞微球10分钟左右可膨胀至干燥状态下直径的4倍。即，干燥时直径为50-100微米的HepaSphere栓塞微球按下述方法重建后，可膨胀为200-400微米。膨胀过程本身充满变数，重建后的栓塞微球会略微超出此范围，因此医生一定要在预期血管闭塞水平和水溶液性质的基础上根据靶血管的粗细谨慎选择栓塞微球大小。

导管相容性

HepaSphere栓塞微球可用下述规格的微导管进行注射：

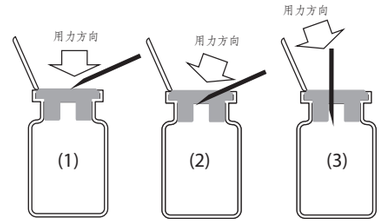
干燥状态下微球直径（μm）	重建后大致直径范围（μm）	导管内径（英寸）
20-40	80 - 160	⩾ 0.020
30-60	120 - 240	⩾ 0.021
50-100	200 - 400	⩾ 0.021

使用说明

HepaSphere 栓塞微球必须用100% 的0.9%生理盐水、或非离子型造影剂、或50%的0.9%生理盐水和50%的非离子型造影剂的混合溶液进行重建。

- 在预期血管闭塞水平和水溶液性质的基础上，根据靶血管仔细选择HepaSphere栓塞微球大小。详见“膨胀性”一节。
- HepaSphere栓塞微球可能会出现在瓶外。因此，必须在远离主无菌区的无菌条件下进行操作。
- 确保HepaSphere栓塞微球与将使用导管的预计大小相匹配。详见上表。
- 检查包装，确认完好无损。从密封袋中取出药瓶。药瓶外表面经灭菌处理。
- 为了防止橡胶塞进入注射针内，请按如下操作：

1. 持针(切面朝上)，将针尖倾斜放在中心穿刺点上，下压针尖顶住中 心穿刺点。
2. 在针尖切面相反的方向轻柔用力将针插入穿刺位置，直至针尖近 端完全插入胶塞。小心针尖不要刮掉橡胶塞。
3. 继续轻柔地用力于针尖切面相反的方向,慢慢地插入针，使其垂直 穿过橡胶帽。
4. 准备完毕后,请仔细检查并确定溶液内是否有橡胶杂质，如溶液内 出现杂质,请勿使用。



栓塞准备

最佳重建时间为10分钟。

- 10ml注射器抽取0.9%生理盐水或非离子型造影剂（或50%的0.9%生理盐水和50%的非离子型造影剂的混合溶液）
- 然后装上直径为20G或以上的针头。
- 为确保栓塞微球充分重建，将药瓶置于水平位，用手指抓住药瓶并摇晃，使瓶内的干燥内容物附于瓶壁。

注： 只可打开翻盖；不要拔下压接环和瓶塞。

- 将注射器针头小心插入瓶塞。继续摇晃药瓶，将溶液全数（10ml）注入药瓶中，然后垂直放置药瓶，小心地拔出针头。

注： 药瓶应密封。 若注射器内溶液不能被自动吸入瓶内，请在注射前小心用注射器从瓶中抽出空气。可采用医疗保健机构认可的适当抽吸与/或排气技术，使溶液更容易注入药瓶中。重建前抽吸药瓶中的空气时，要特别小心，以免吸出瓶中的微球。

- 摇动药瓶，使液体接触瓶塞5-10次，确保HepaSphere栓塞微球制备均匀。
- 至少等待10分钟，使HepaSphere栓塞微球充分制备并膨胀。
- 用30ml注射器和直径为20G或以上的针头抽取瓶中的内容物。将药瓶旋转至垂直位置，瓶底向上。向下拉针头，使其浸没在液体中，但不可没入瓶塞。将瓶中的内容物全部吸入注射器中。

注： 若瓶内的空气已预先抽出，抽取瓶中的内容物之前，可用注射器缓慢注入空气，确保内容物的抽取更加容易。若内容物未完全吸出，可注入更多空气，并重复抽取过程。注射器中可加入额外的非离子型造影剂或0. 9%的生理盐水，以便得到分散较好的微球。

- 如用100%的0. 9%生理盐水重建微球，那么必须在装有HepaSphere栓塞微球的注射器中加入非离子型造影剂，使其在荧光屏透视下显影。用非离子型造影剂制备微球时，可添加额外的非离子型造影剂。

输注说明

- 利用高分辨率成像认真评估与靶病变相关的血管网。

注： 开始栓塞前，确定是否存在动静脉分流至关重要。

- 用标准技术将输送导管置入靶血管内，导管头尽量靠近栓塞靶部位。
- 用不超过3ml的注射器推注HepaSphere微球。建议最好使用1ml注射器。
- 用注射器抽取 HepaSphere栓塞微球混合剂。
- 可以用两种方法抽取等分栓塞微球进行栓塞，以便注射：

方法1： 将装有HepaSphere栓塞微球的30ml注射器、三通阀、微导管连接到一起，用1m注射器通过三通阀进行注射。

方法2： 用1ml注射器通过未连接微导管的三通阀从30 ml注射器中抽取等分栓塞微球。将装有栓塞微球的1 ml注射器连接至微导管并注射。

- 摇动30 ml注射器，使HepaSphere栓塞微球混合剂保持均匀悬浮状态。
- 在X线持续引导下，以脉动方式缓慢注射HepaSphere栓塞微球，不可用力，注射速度约为1分钟/ml。始终在自由流动条件下注射，并监测返流。

注： 栓塞微球返流可能导致非靶组织和血管的急性缺血。

- 如果HepaSphere栓塞微球输注过程中，供血蒂血流停滞，请至少等待5分钟，然后在等待整整5分钟之后进行选择性血管造影，确认前向血流是否停止。
- 如果前向血流并没有停止，则继续在荧光屏透视的引导下注射，直至实现预期的血流阻断。
- HepaSphere 微球注射完毕后，在保持轻缓抽吸的同时移除导管，以免导管腔内残留的栓塞微球流出。导管移除后即废弃，不可再次使用。
- 开封药瓶或未用完的栓塞微球应丢弃。

小心

如果导管阻塞或注射过程中遇到明显的阻力，切勿施加过大压力冲洗导管，否则栓塞材料可能会返流，导致非靶组织栓塞。保持轻微抽吸状态，同时移除导管并丢弃。

保存和贮藏

HepaSphere栓塞微球必须以原始药瓶和包装保存在干燥阴凉处。于标签上标注的日期前使用。

栓塞微球重建完成后，若不立即使用，应2-8℃保存并在24小时内使用。添加造影剂后，不可存放。

干燥微球直径（μm）	颜色编号（标签边缘）	微球量（mg）	型号
20-40	灰色	15 25 50	V115 HS V125 HS V150 HS
30-60	橙色	15 25 50	V 215 HS V 225 HS V 250 HS
50-100	黄色	15 25	V315 HS V325 HS

图形符号等说明：

图形符号	说明
	失效日期
LOT	批号
REF	产品编号
	不得二次灭菌
	如包装破损切勿使用
	怕晒
	怕雨
	不得二次使用
	警告
	无热原
STERILE R	辐照灭菌
•/●	干燥状态下微球尺寸/ 水合后的微球尺寸

产品名称：栓塞微球

有关HepaSphere栓塞微球使用的严重或危及生命的不良事件或死亡均应报告制造商。

生产日期和失效日期：见产品标签

有效期： 3年；

储存条件：室温，通风，干燥，避光；

运输条件：运输过程中，避免接触高温潮湿；

注册证编号/产品技术要求编号：国械注进20153133115

中国境内代理人及售后服务单位名称：麦瑞通医疗器械（北京）有限公司

中国境内代理人及售后服务单位住所：北京市朝阳区东大桥路9号楼2单元801室内B01、B02 及B03单元

中国境内代理人及售后服务单位电话：010 - 85610788

中国境内代理人及售后服务单位传真：010 - 85616981

注册人及生产企业名称：百奥斯菲医疗器械有限公司 BIOSPHERE MEDICAL S. A

注册人及生产企业住所：Parc des Nations-Paris Nord 2, 383 rue de la Belle Etoile, 95700 Roissy en France-FRANCE

生产地址：Parc des Nations-Paris Nord 2, 383 rue de la Belle Etoile, 95700 Roissy en France-FRANCE

注册人及生产企业联系方式： 33(0) 1 48 17 25 25

说明书编制或修订日期： 2024年11月

型号、规格：

型号：V315HS，规格：15mg，尺寸：50-100μm；
型号：V325HS，规格：25mg，尺寸：50-100μm；
型号：V215HS，规格：15mg，尺寸：30-60μm；
型号：V225HS，规格：25mg，尺寸：30-60μm；
型号：V250HS，规格：50mg，尺寸：30-60μm。
型号：V125HS，规格：25mg，尺寸：20-40μm；
型号：V150HS，规格：50mg，尺寸：20-40μm。
型号：V115HS，规格：15mg，尺寸：20-40μm。

结构及组成：该产品是由丙烯酸聚合物（乙烯醇-丙烯酸钠: vinylalcohol - sodium acrylate）制成。辐照灭菌，一次性使用。货架有效期3年。