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Medtronic

Aortic Punch

Sacabocados aórtico
Аортен перфоратор
Перфоратор аорты
Aortní probojac
Перфоратор аорти

400, 500

Instructions for Use • Instrucciones de uso •
Упатства за употреба • инструкция по применению •
Uputstva za upotrebu • Інструкція з експлуатації

USA **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

CE 0123

Explanation of symbols on package labeling / Explicación de los símbolos que aparecen en la documentación del envase / Објаснување на симболите од етикетата на пакувањето / Объяснение символов на этикетках упаковки / Objašnjenje simbola na oznakama na pakovanju / Пояснення символів на маркуванні упаковки

Refer to the device labeling to see which symbols apply to this product. / Consulte la documentación del dispositivo para comprobar qué símbolos se utilizan con este producto. / Проверете ја етикетата на помагалото за да видите кои симболи се однесуваат на овој производ. / См. на этикетках устройства, какие символы применимы к данному продукту. / Pogledajte spoljnu oznaku na pakovanju da biste videli koji se simboli primenjuju na ovaj proizvod. / Дивіться маркування пристрою, щоб визначити, які символи стосуються цього виробу.

CE	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union Acts. / Conformité Européenne (Conformidad Europea). Este símbolo indica que el dispositivo cumple totalmente las Directivas europeas pertinentes. / Сообразност со европските стандарди. Овој симбол значи дека помагалото е целосно сообразно со важечките закони на Европската унија. / Conformité Européenne (Европейское соответствие). Этот символ обозначает, что устройство полностью соответствует требованиям применимых директив Европейского Союза. / Conformité Européenne (usklađenost sa evropskim standardima). Ovaj simbol znači da je uređaj u potpunosti usklađen sa važećim zakonima Evropske unije. / Conformité Européenne (Європейська відповідність). Цей символ означає, що пристрій повністю відповідає вимогам застосовних директив Європейського Союзу.
STERILE R	Sterilized using irradiation / Esterilizado mediante irradiación / Стерилизирано со зрачење / Стерилизовано излучением / Sterilisano zračenjem / Стерилізовано опроміненням
	Use-by date / Fecha de caducidad / Употребено до / Срок годности / Datum „Upotrebljivo do" / Термін придатності
LOT	Lot number / Número de lote / Број на серија / Номер партии / Broj serije / Номер партії
	Do not reuse / No reutilizar / Само за еднократна употреба / Не использовать повторно / Nije za ponovnu upotrebu / Не застосовувати повторно
	Do not resterilize / No reesterilizar / Да не се стерилизира повторно / Не стерилизовать повторно / Nije za ponovnu sterilizaciju / Не стерилізувати повторно
! USA	For US audiences only / Solo aplicable en EE. UU. / Намението само за корисници во САД / Только для США / Samo za korisnike u SAD / Лише для користувачів у США
	Model / Modelo / Модел / Модель / Model / Модель
	Size / Tamaño / Големина / Размер: / Veličina / Розмір
REF	Catalog number / Número de catálogo / Каталошки број / Номер по каталогу / Kataloški broj / Номер у каталозі
	Do not use if package damaged / No utilizar si el envase está dañado / Да не се употребува доколку пакувањето е оштетено / Не использовать, если упаковка повреждена / Ne koristiti ako je pakovanje oštećeno / Не використовувати, якщо упаковка пошкоджена
	Date of manufacture / Fecha de fabricación / Датум на производство / Дата изготовления / Datum proizvodnje / Дата виготовлення
EC REP	Authorized representative in the European Community / Representante autorizado en la Comunidad Europea / Овластен претставник во Европската заедница / Уполномоченный представитель в Европейском сообществе / Ovlašćeni predstavnik u Evropskoj zajednici / Уповноважений представник у Європейському Співтоваристві
	Keep away from heat / Mantener alejado del calor / Да се чува подалеку од топлина / Не хранить вблизи источников тепла / Držati podalje od izvora toplote / Тримати подалі від джерел тепла
	Keep dry / Mantener seco / Да се чува на суво место / Хранить в сухом месте / Držati na suvom / Зберігати у сухому місці
	Quantity / Cantidad / Количина / Количество / Količina / Кількість
	Manufactured in / Fabricado en / Произведено во / Произведено в / Proizvedeno u / Місце виготовлення
	Manufacturer / Fabricante / Производител / Произвођач / Proizvođač / Виробник

Figure 1 / Figura 1 / Слика 1 / Рисунок 1 / Slika 1 / Рисунок 1

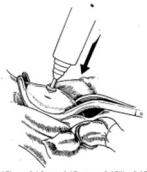

Figure 2 / Figura 2 / Слика 2 / Рисунок 2 / Slika 2 / Рисунок 2

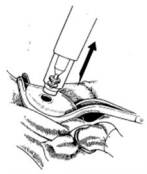

Figure 3 / Figura 3 / Слика 3 / Рисунок 3 / Slika 3 / Рисунок 3

Aortic Punch

1. Device description

The Medtronic aortic punch is a disposable surgical instrument designed to produce a clean, circular opening in the aortic wall to facilitate anastomosis for revascularization.

The Medtronic aortic punch is available in 2 different handle lengths.

- Model 400, standard length handle (109 mm)
- Model 500, long length handle (160 mm)

2. Indications for use

The Medtronic aortic punch is intended for use by cardiac surgeons during coronary artery bypass grafting procedures to create an opening in the wall of the vessel.

3. Contraindications

No contraindications for use of this device are known.

4. Warnings and precautions

4.1. Warnings

This device was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device or create a risk of contamination of the device, which could result in patient injury, illness, or death.

4.2. Precautions

- The aortic punch is a cutting instrument and contains sharp edges near the punch tip. Use caution to avoid unintended injury from the sharp edges of the punch.
- Inspect the sterile package before use. If there is damage to the package (for example, holes, punctures, or the seal is broken), do not use the device. Contact your local Medtronic representative.
- Do not use the product after its expiration date.
- Inspect the aortic punch before use. Do not use the device if there is damage to the handle or punch tip such as cracking or missing pieces.
- The sterile package is a single-barrier pouch. Dispose of the aortic punch in accordance with hospital biohazard requirements.

5. Potential adverse events

- Bleeding
- Embolism
- Immunotoxic response
- Infection

6. Instructions for use

Note: Remove the adventitia before making the initial (scalpel) incision to improve the performance of the aortic punch.

1. Activate the punch several times before surgical use.
2. Apply a deep, side-biting vascular clamp or other appropriate instrument to the aorta. Make an incision approximately 1 mm smaller than the punch tip diameter in the occluded portion of the vessel (Figure 1).
3. Hold the punch perpendicular to the aortic wall. Center and insert the punch tip in the incision (Figure 2).

4. Push the plunger toward the handle in the manner of a hypodermic syringe. There will be an audible snap as the die cylinder passes the punch tip, producing a clean, circular hole.
5. To ensure removal of the excised aortic tissue plug, remove the punch from the aorta without releasing the plunger (Figure 3).

Note: One aortic punch can be used to make a number of openings for a coronary artery bypass procedure. After the punch is removed from the aorta, release the plunger and remove the excised plug from the punch before using it for an additional opening. Do not resterilize or reuse the aortic punch. The aortic punch is intended for single patient use only.

7. How supplied

7.1. Packaging

The Medtronic aortic punch is supplied sterile (by gamma radiation), individually packaged, 6 per box. Do not use the punch if the sterile package is damaged.

7.2. Available sizes

Both models of the Medtronic aortic punch are available in the following diameters: 2.5 mm, 3.0 mm, 3.5 mm, 4.0 mm, 4.4 mm, 4.8 mm, 5.0 mm, 5.2 mm, 5.6 mm, and 6.0 mm.

8. Disclaimer of warranty

THE FOLLOWING DISCLAIMER OF WARRANTY APPLIES TO UNITED STATES CUSTOMERS ONLY:

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