Super Ketch ™ - Speed Ketch ™

STERILE, SINGLE USE ONLY. Sterilized with ethylene oxide gas. Non pyrogenic. Do not resterilize. Do not use opened or damaged packages. Destroy product after use. Store in a dry place between 0°- 40° C, keep away from light. Read instructions prior to use.

1 Description

1.1 Y connectors

The **Super Ketch™** and **Speed Ketch™** are Y connectors comprising a tricuspid star shaped valve, designed to provide haemostatis during endovascular procedures. The **Super Ketch™** and **Speed Ketch™** include a straight and a side access lumen.
The haemostatic valve, located at the proximal end of the straight lumen, can be opened and closed by operation of the “push-pull” button valve. The distal end has a rotating male luer lock.
The side access lumen allows pressure monitoring and perfusion.
The side access lumen of the **Speed Ketch™** ends with a female luer lock, and the one of the **Super Ketch™** with a side arm tubing ending by a standard three-way stopcock.

1.2 Metallic Insertion Tool

The metallic insertion tool is an accessory designed to facilitate the introduction of guidewires (up to 0.018”) used in conjunction with interventional devices during vascular interventional procedures.

1.3 Plastic Insertion Tool

This accessory is designed to facilitate the introduction of (up to 3 French) catheters through the haemostatic valve.

1.4 Torquer

This device is designed to facilitate steering of 0.010’’ to 0.035’’ guidewires.

1.5 Product specifications

Components Specifications		
Speed Ketch™ / Super Ketch™	Inner Lumen Compatibility	7F / 0.092’’ / 2.33 mm maximum
	Pressure Resistance[(1)] after introduction of a device	8 atm. maximum
Metallic Insertion Tool	External Diameter	2.7 F / 0.90 mm
	Inner Lumen Diameter	1.9 F / 0.025’’ / 0.64 mm
	Usable Length	10 cm
Plastic Peelable Insertion Tool	Length	9 cm
	Inner Diameter	3.4 F / 0.44’’ / 1.14 mm
Torquer	Guidewire Compatibility	From 0.010’’ minimum to 0.035’’ maximum

[(1)] Haemostatic valve resistance measured in vitro, by applying injection pressure through the side port.

08020034 Rev.2011-03

2 Indications

The **Super Ketch™** and **Speed Ketch™** Y connectors are intended to maintain haemostatis before and during the introduction / the use and withdrawal of diagnostic / interventional devices with outside diameter ≤ 7F (2.33 mm, 0.092'') during interventional procedures.

3 Warnings

- The **Super Ketch™** or **Speed Ketch™** devices should exclusively be used by physicians trained in interventional procedures. It is recommended to the physician to consult current peer-reviewed publications on the interventional techniques.

4 Precautions

- This device is designed and intended for single use only. In case of re-use, device sterility shall be lost and performances altered. Do not resterilise or reuse it. Use prior to the "use before" date noted on the packaging.
- Inspect the **Super Ketch™** or the **Speed Ketch™** prior to use. Do not use opened or damaged packages.
- Ensure that the **Super Ketch™** or **Speed Ketch™** is flushed correctly and all air removed before use (refer to Chapter 7 Instructions for use). Any aspiration through the side access of the **Super Ketch™** or **Speed Ketch™** should be effectuated slowly and carefully to avoid the creation of a void in the proximal part of the connector, leading to an effect of suction on the haemostatic valve.
- Always open the haemostatic valve using the push-pull button valve opener before inserting any device with a fragile distal portion, in order to avoid damage of the product when passing through the valve.
- Always retrieve the metallic insertion tool before retrieval of the guidewire, to avoid any damage of the guidewire.
- The metallic insertion tool should be inserted carefully through the valve in order not to damage or dislodge it.
- Do not attempt to force a device with an external diameter larger than 7 French (2.33 mm, 0.092'') through the haemostatic valve.

5 Contra-indications

No specific contra-indications for the use of the **Super Ketch™** and **Speed Ketch™** Y connectors.

6 Adverse events

Potential complications include, but are not limited to:

- Contrast crystal formation
- Clotting
- Emboli

7 Instructions for use

- Connect the **Super Ketch™** or **Speed Ketch™** side access to the perfusion (manifold) device using a stopcock if needed (**Speed Ketch™**).
- Set up continuous flush with a normal saline solution to remove trapped air and connect the male rotating luer lock of the **Super Ketch™** or **Speed Ketch™** to the guiding catheter or any other device chosen by the operator.

- To flush the connector segment comprising the valve, open the haemostatic valve by pushing the push-pull button valve opener and continue to fill the assembled devices. To close the valve, pull-out the push-pull button valve opener into its original position.

  Make sure by visually checking that no air bubble is trapped into the **Super Ketch™** or **Speed Ketch™** device.

- Aspirate any air that may have entered the system before the introduction of the devices, to make sure that no air bubble has been captured.

- Establish pressure above arterial pressure in order to prevent any retrograde flow of blood into guiding catheter or any other device chosen by the operator. Check that all connections are secure so that air is not introduced during continuous flush.

- Introduce the guiding catheter or any other device chosen by the physician following the recommendations of respective device manufacturers.

- Insert the guidewire, or the guidewire and dilatation catheter together, or any chosen device into the **Super Ketch™** or **Speed Ketch™** straight lumen.

  The valve shall be opened using the push-pull button valve opener, when any device is inserted through the valve into the straight lumen of the **Super Ketch™** or **Speed Ketch™**.

  - The metallic insertion tool supplied with the **Super Ketch™** and **the Speed Ketch™** must be used when the guidewire alone is inserted through the valve, in order to protect the guidewire distal tip.
  - The plastic insertion tool provided with the **Speed Ketch™** must be used when a microcatheter alone is introduced through the valve, in order not to damage the device when passing through the closed valve.

- Perform the rest of the procedure following the recommendations of respective device manufacturers.

Note: When introducing or retrieving devices, it is important to manipulate the devices slowly and with care. Rapid accelerations can provoke a suction phenomenon at the level of the valve, which could introduce air into the system.

Torquer instructions for use

- The maneuverability of the guidewires when introduced through the inner lumen of **Super Ketch™** can be improved by the use of the Torquer supplied as an accessory (**Super Ketch™ Plus**).

- Positioning / moving procedure:

  Unscrew the cap of the Torquer.

  Insert the proximal end of the guidewire into the funnel-shaped hole on the distal end of the Torquer. Once the Torquer is positioned at the desired location, tighten the Torquer to secure the Torquer to the guidewire.

  To move the Torquer to a new position, loosen the proximal end of the Torquer, slide the device along the guidewire to the desire location, and tighten the Torquer.

8 Sterilisation and Storage conditions

- STERILE. Sterilised with Ethylene Oxide Gas. Non pyrogenic.
- **Super Ketch™** and **Speed Ketch™** Y connectors are delivered in an individual peelable pouch. 10 units are delivered per cardboard box.

- Use before the expiry date clearly indicated on the label.
- Store at room temperature below 40°C, in a dry place, protected from light.

9 Liability

Minvasys has endeavoured to ensure that the products comply with all relevant standards and regulations currently in force and to ensure that the quality of the products meets the requirements of the above mentioned standards and regulations for a period ending upon the indicated expiry date. The above statement does not apply when the products are used for a purpose other than its intended purpose. Where any loss or damage is caused (other than death or personal injury) due to a defective product, Minvasys shall not be liable for such loss or damage.

10 Conversion Chart

1 French	0.0131''	0.33 mm	
1cc	1mL	10^{-6} m^3	
1 bar	1.02 atm.	14.5 PSI	10^5 Pa

11 Symbols

Quantity per package

Maximum inner diameter

Do not use damaged packaging

Do not resterilize

CE 0459 Year CE marking obtained: 2004

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