LIPIODOL® RESISTANT Medical Devices

Ethyl ester of iodized fatty acids of poppy seed oil

UNBREAKABLE | USER-FRIENDLY | SHARP

Guerbet

LIPIODOL® RESISTANT medical devices list

1mL SYRINGE

Reference: QIT001

3mL SYRINGE

Reference: QIT002

20mL SYRINGE

Reference: QIT003

STOPCOCK

Reference: QIT004

15µm FILTER STRAW

Reference: QIT005

BENEFITS

Lipiodol® Resistance
Up to 24h [1,2]

Safety
Reduce liquid exposure [2]

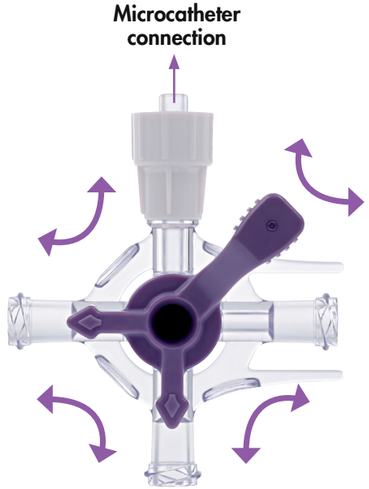
Easy to use
User friendly

1. Internal Test Report E17-41 (2017)
2. Internal Test Report E20-13 (2020)

LIPIODOL® RESISTANT 4-Way Stopcock

Lipiodol® resistance

- ✓ Lipiodol® 24H resistance [1,2]
- ✓ Prevent leakage [2]
- ✓ Pressure resistance [2]
- ✓ Avoid air injection



4 ports allow connections with 3 syringes & 1 Microcatheter

Transparent stopcock allows air bubbles visualization

1. Internal Test Report E17-41 (2017)
2. Internal Test Report E20-13 (2020)

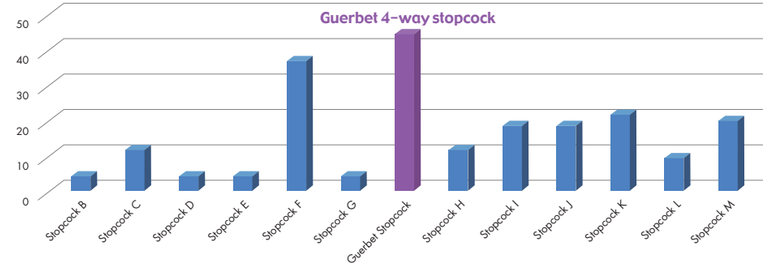
Performance of LIPIODOL® RESISTANT 4-Way Stopcock

STOPCOCK

Pressure resistance test – Guerbet Lipiodol® resistant 4-way stopcock VS 12 other stopcocks

- Stopcocks are exposed to Lipiodol® 3 hours before the pressure resistance test

Pressure resistance (Bars) **after 3 hours exposure to Lipiodol®**



TEST RESULT [2]

Only Guerbet Lipiodol® resistant 4-way stopcock can resist to pressure >38 bars without break.

GUERBET 4-WAY STOPCOCK CAN RESIST HIGHER PRESSURE THAN STANDARD STOPCOCKS

2. Internal Test Report E20-13 (2020)

LIPIODOL® RESISTANT 1 ml & 3 ml Syringes

Lipiodol® resistance

- ✓ Lipiodol® 24H resistance [1,2]
- ✓ Prevent leakage [2]
- ✓ Pressure resistance [2]
- ✓ Ergonomic design

Plunger
Ergonomic design for optimal grip and easy injection

Backstop (Patented)
Prevents accidental release

Rotary finger support
Obtain more suitable working position

- **O-ring design** – Sealing function
- **Elimination of the elastic zone**
  Tactile feedback improvement, direct transmission of forces from hand to liquid

Luer lock

1. Internal Test Report E17-41 (2017)
2. Internal Test Report E20-13 (2020)

LIPIODOL® RESISTANT 20 ml Syringes

Lipiodol® resistance

- ✓ Lipiodol® 24H resistance [1,2]
- ✓ Prevent leakage [2]
- ✓ Pressure resistance [2]
- ✓ Ergonomic design

Plunger
Ergonomic convex shape, rotatable, atraumatic for the palm & fingers

Backstop (Patented)
Prevents accidental release

Rotary finger support
Adjustable working position after connection

- **O-ring design** – Sealing function
- **Elimination of the elastic zone**
  Tactile feedback improvement, direct transmission of forces from hand to liquid

Luer lock

1. Internal Test Report E17-41 (2017)
2. Internal Test Report E20-13 (2020)

Performance of LIPIODOL® RESISTANT 1 ml Syringe

Pressure resistance test

1ml SYRINGE

Breakage/leak rate test – Lipiodol® resistant 1 mL syringes VS standard syringes

	Standard syringe C (1mL)	Guerbet Lipiodol® resistant syringe (1mL)
Step 1 Contact with Lipiodol®	1.5 Hours	**24 Hours**
Step 2 Apply pressure to syringes	39 bars	**78 bars**
TEST RESULT[2]	**100%** Breakage/leak rate after exposure to Lipiodol®	**0%** Breakage/leak rate after exposure to Lipiodol®

2. Internal Test Report E20-13 (2020)

Performance of LIPIODOL® RESISTANT 20 ml Syringe

Pressure resistance test

20ml SYRINGE

Breakage/leak rate test – Lipiodol® resistant 20 mL syringes VS standard syringes

	Standard syringe B (20mL)	Guerbet Lipiodol® resistant syringe (20mL)
Step 1 Contact with Lipiodol®	1.5 Hours	**24 Hours**
Step 2 Apply pressure to syringes	4.1 bars	**4.3 bars**
TEST RESULT[2]	**60%** Breakage/leak rate after exposure to Lipiodol®	**0%** Breakage/leak rate after exposure to Lipiodol®

LIPIODOL® RESISTANT SYRINGES CAN RESIST HIGHER PRESSURE THAN STANDARD SYRINGES AFTER EXPOSURE TO LIPIODOL®

2. Internal Test Report E20-13 (2020)

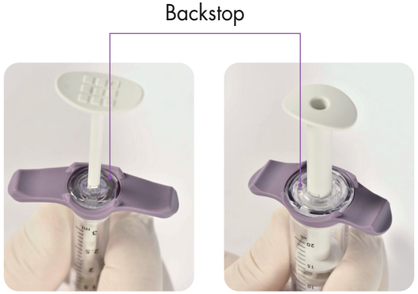
Performance of LIPIODOL® RESISTANT Syringes

Prevent liquid exposure

SYRINGES

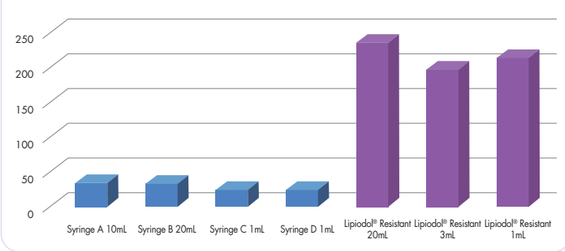
Anti-ejection design in Lipiodol® resistant syringes

- **The backstop in Lipiodol® resistant syringes (1mL/3mL/20mL) avoids the exposure & ejection of plunger from the syringes**



Guerbet Lipiodol® resistant syringes (1mL/3mL/20mL)

Performance test of backstop
Traction on plunger (N)



TEST RESULT [2]

Backstops make Guerbet Lipiodol® resistant syringes holding around **200 N** of traction. The standard syringes can just hold less than **35 N**.

GUERBET LIPIODOL® RESISTANT SYRINGES CAN REDUCE THE RISK OF LIQUID EXPOSURE & PLUNGER EJECTION

2. Internal Test Report E20-13 (2020)

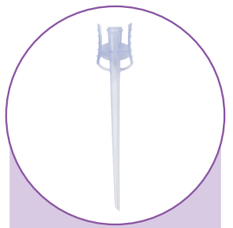
LIPIODOL® RESISTANT 15µm Filter Straw

24H LIPIODOL® RESISTANT
Device functionality verified up to 24 h in contact with Lipiodol®

Particle filter | **Straw**

Lipiodol® Resistant

15µm filter retains glass particles that may be released when breaking ampoule



Lipiodol® Ultra Fluid ampoule withdrawing straw

Connection with syringe for withdrawing Lipiodol®

LIPIODOL® Specifications Maintained

- **Lipiodol® standard production specifications:** **Absorbance:** 420nm: ≤0.60 ; 460nm: ≤0.50
  Acid value: ≤1.0mg KOH/g

Lipiodol® batch #	Time of contact	Absorbance 420nm (≤0.60) 460nm(≤0.50)		Acid value (≤1.0mg KOH/g)
Lipiodol® batch 15LF604A	24H	0.25	0.14	0.7
Lipiodol® batch 16LU604A		0.19	0.10	0.5
Lipiodol® batch 14LU607A		0.28	0.17	0.6

TEST RESULT[3]

Lipiodol® remains under its specification limits after 24H of contact with Guerbet Lipiodol® resistant syringes and stopcock.

3.Internal Test Report 2_17_00401-1.0(2017)v

Features & benefits

Features	Benefits
Lipiodol® Resistant & Unbreakable	• **Safety** – Closed system to reduce risks of leakage[2] • **Swiftness** – No devices break & no devices change
Ergonomic & User-Friendly ✓ Syringe backstop ✓ Rotary finger grip ✓ Optimized-handling 	• **Safety** – No syringe pull-back & no liquids projection • **Accuracy** – Easy-to-handle & sharp • **Swiftness** – Easy-to-inject • **Convenience** – Ready-to-use
4-Way Stopcock System ✓ Unique 4-way stopcock 	• **Safety** – Reduced risks of infection, air injection, leaks[2] • **Swiftness** – less connection mistakes & no disconnection time • **Convenience** – On-table Refill & optimized injection control

2. Internal Test Report E20-13 (2020)

Precautions For Use

SYRINGES

Apply pressure:
Apply axial controlled pressure on the syringe's plunger to avoid uncontrolled injection and damage to the device.

Injection:
Plunger of 1 mL syringe should not be pushed by both hands

STOPCOCK

Maximal pressure:
Lipiodol® resistant stopcock **can resist up to 38 Bars[4] of pressure with no risk of exposure**. The force applied by a human hand on a 1mL syringe may exceed this limit, so pressure on the plunger should be moderate during the process. If drops appear in the center of the stopcock, a pressure exceeding the limit of 38 Bars occurred. Note that the stopcock is not broken and remains usable.

Connection with luer lock:
All Luer connections should be gently hand tightened without over tightening to ensure their security and to prevent damage to the device

4. IFU of stopcock

Guerbet LIPIODOL® RESISTANT syringes & stopcock patents

- Backstops in Lipiodol® resistant syringes PATENTED
- Ergonomics for Lipiodol® resistant syringes PATENTED
- The connection with Lipiodol® resistant stopcock PATENTED
- Lipiodol® resistant stopcock safety belt PATENTED

Lipiodol® resistant medical devices are medical devices intended for use by healthcare professionals only.

Intended use (Syringes): Single use syringe, intended for injecting fluids into the body, manually, during procedures using Lipiodol® Ultra Fluid

Intended use (Stopcock): Single use device intended for fluid flow directional control and for providing access ports for administration of Lipiodol® Ultra Fluid

Intended use (Filter Straw): Single use device intended for needleless access to sterile Lipiodol® Ultra Fluid ampoules

For complete information about precautions and optimal usage conditions, we recommend consulting the instruction for use supplied with the device or by your local Guerbet representative(s). For use only in countries with applicable health authority registrations

Class Is/CE

GMED 0459

Manufacturer: Medex

References

1. Internal Test Report E17-41 (2017)
2. Internal Test Report E20-13 (2020)
3. Internal Test Report 2_17_00401-1.0(2017)
4. IFU of stopcock

Check Lipiodol® Ultra Fluid summary of product information at:

Guerbet

P20000150 - May 2020 - Photos : Guerbet annapurna8000