

Perfecting Performance



Occlutech[®]

Sheath sizes: AGA vs. Occlutech
UPDATE

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Measured Values

BACKGROUND

Some doctors still refuse to use our products, stating that AGA Occluders need smaller sheath sizes. They refer to the inner diameter of a sheath system without noticing that the outer diameter is significantly larger compared to the Occlutech delivery set.

AIM OF WORK

To show that AGA's information regarding sheath diameter is misleading and that Occlutech is comparable or even smaller.

METHODS

Measure the outer diameter of each sheath size (with the help of a microscope).

RESULTS

The outer diameter of the AGA sheaths is always larger compared to Occlutech's delivery set.

CONCLUSION

Inner diameter is labeled on the product but outer diameter is what makes the sheath and is introduced into the patient. The Occlutech delivery sheath has a smaller outer diameter compared to the AGA TorqVue.

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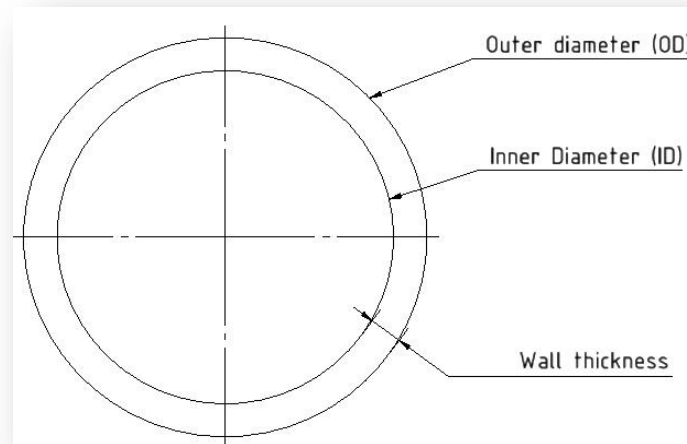
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Measured Values

Basics

- ✓ The outer diameter is what makes the sheath and is introduced into the patient
- ✓ The outer diameter of each sheath size has been measured (using a microscope)

	AGA	Occlutech
<i>Sheath SIZE [F]</i>	<i>Measured OD[mm]</i>	<i>Measured OD[mm]</i>
7	3,4	3,0
8	3,7	3,3
9	4,0	3,9
10	4,4	4,1
11	4,6	4,2
12	4,9	4,6



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Sheath sizes: AGA vs. Occlutech

Measured Values

	AGA	Occlutech	Difference*	
Sheath SIZE [F]	Measured OD[mm]	Measured OD[mm]	[mm]	[F]
7	3,4	3,0	+0,4	+1.33
8	3,7	3,3	+0,4	+1.33
9	4,0	3,9	+0,1	+0.33
10	4,4	4,1	+0,3	+1.00
11	4,6	4,2	+0,4	+1.33
12	4,9	4,6	+0,3	+1.00

* reference=Occlutech sheath

How to read the values mentioned above:

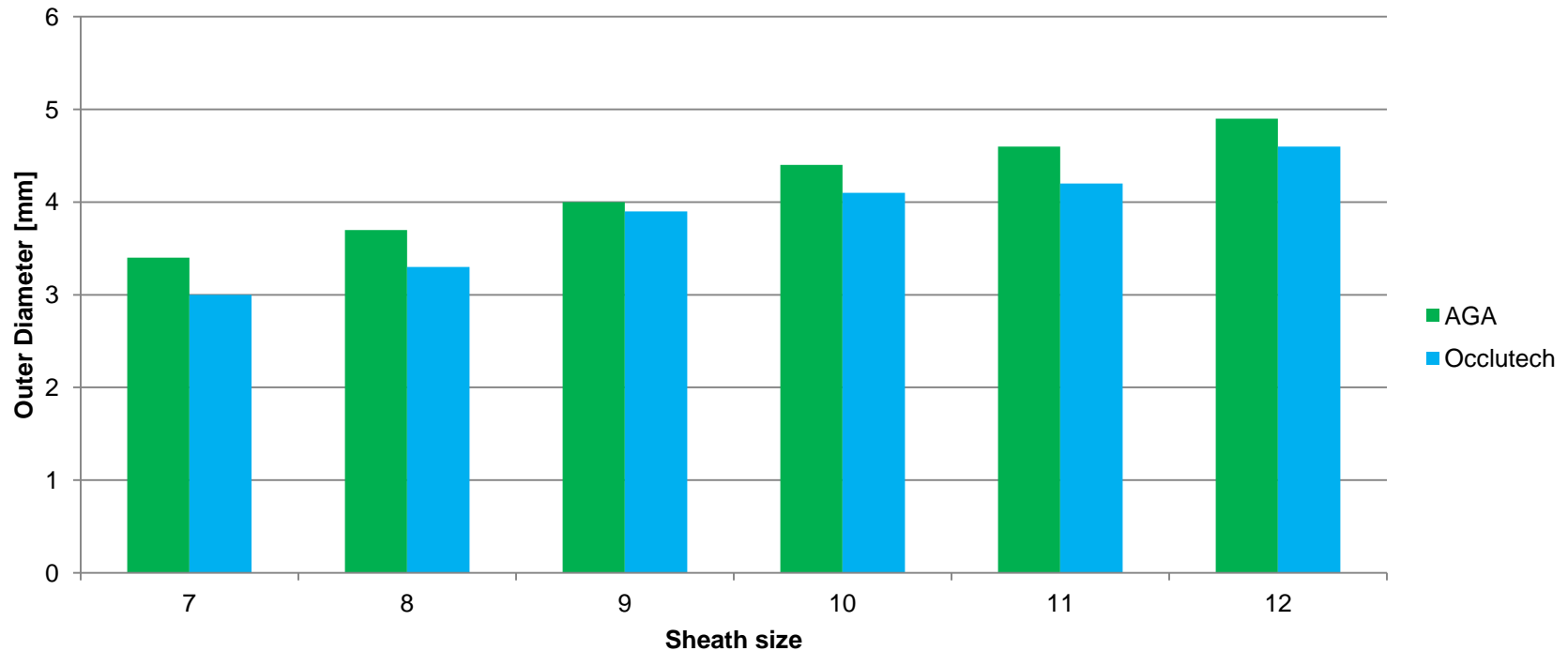
- ✓ The outer diameter of a 7F AGA sheath is larger than a 8F Occlutech sheath.
- ✓ The outer diameter of an 8F AGA sheath is almost as big as the 9F Occlutech sheath.
- ✓ The outer diameter of a 9F AGA sheath is comparable to a 9F Occlutech sheath.
- ✓ The outer diameter of a 10F AGA sheath is close to a 12F Occlutech sheath
- ✓ The outer diameter of an 11F AGA sheath is comparable to a 12F Occlutech sheath
- ✓ The outer diameter of a 12F AGA sheath is 1F larger than the comparable 12F Occlutech sheath

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Measured Values

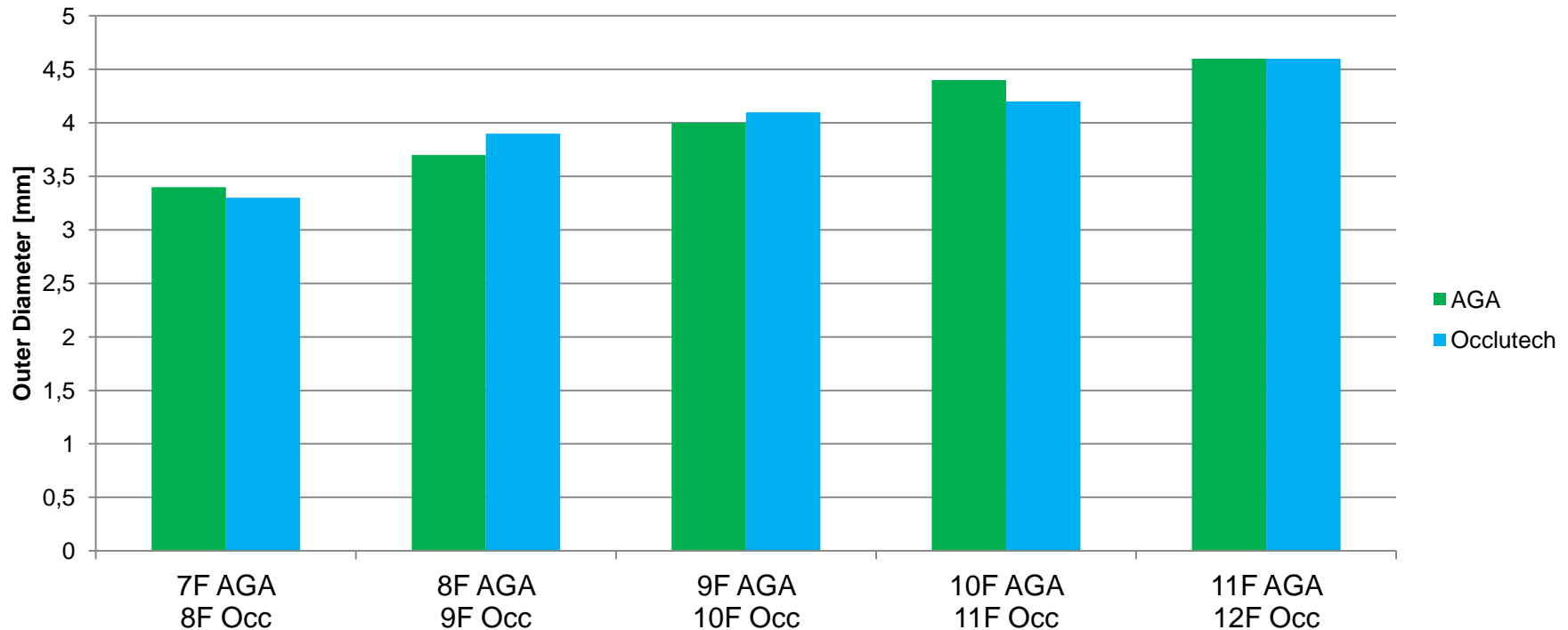


Comparing the same size, the AGA sheaths are always larger than Occlutech.

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Measured Values



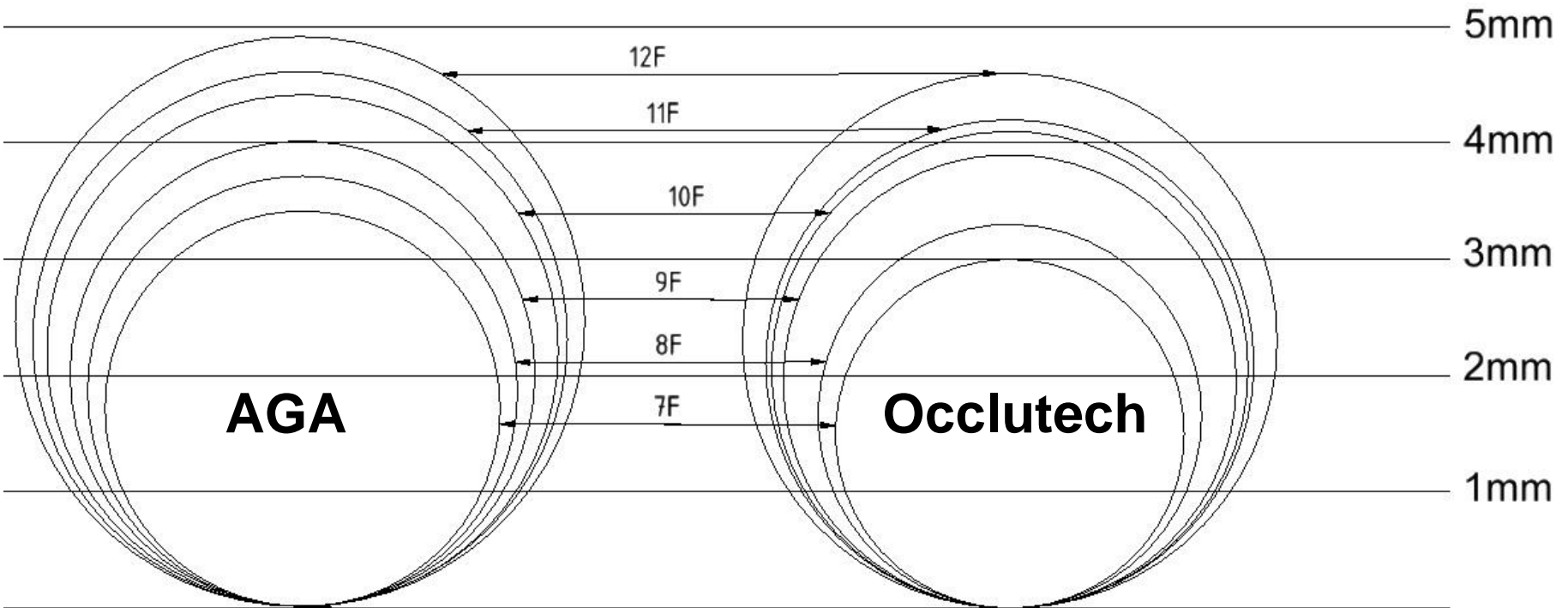
Comparing AGA sheaths against 1F larger Occlutech sheath shows that we are mostly smaller or even at the same diameter.

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Sheath sizes: AGA vs. Occlutech

Difference in diameters

The drawing below shows graphically the difference on the **actual outer diameters** of AGA and Occlutech sheaths.



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Final conclusion

Facts

- The label on the catheter system always mentions the **INNER DIAMETERS** of the sheath
- **The OUTER AND INNER DIAMETER AGA is advertising are misleading and not accurate**
- Asking several KOL's like Ziyad Hijazi, Nik Haas, Trong Phi Le (Bremen/Germany) and Gareth Morgan (Denver/Colorado) about their input regarding sheath sizes. They all responded the same:
 - It's more important to ensure a safe deployment and low forces to advance the occluder
 - The statement regarding "the smaller the better" is a gentle argument of denial
 - Due to **venous access**, sheath size is not that important (only in case of neonates)

Bottom Line

- Occlutech sheaths are always smaller than AGAs → The difference between the sheaths is 0,3 up to 1,3F
- Doctors should be informed that AGA sheaths have a significant larger outer diameter than comparable Occlutech sheaths
- Based on the values for the outer diameter the following table represents the realistic proportion:

AGA		Occlutech
		7F
7F	=	8F
8F	=	9F
9F	=	10F
10F	=	11F
11F	=	12F
12F		

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