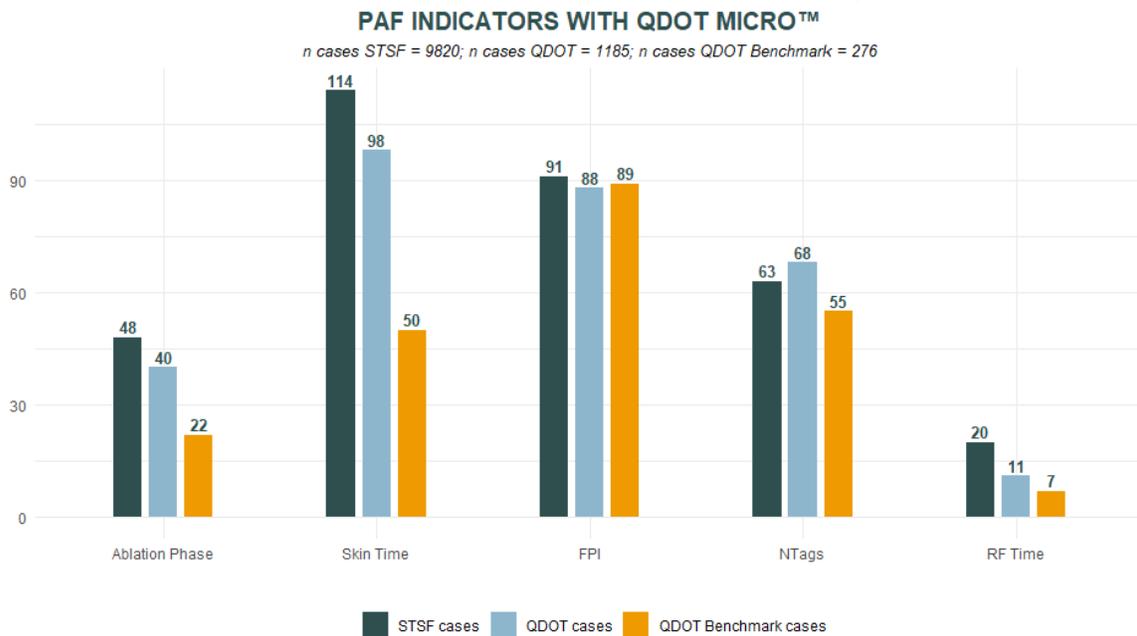


QDOT MICRO™ Catheter Data Report

Data recording tools (LOT/CARTODAY™ Application) allow for collection of CARTO™ 3 System procedure metrics including procedure time (Skin time), Ablation phase time, First Pass Isolation (FPI) and number of Visitags (nTags). These metrics are logged by Biosense Webster, Inc. Clinical Account Specialists during each case. Participation in LOT/CARTODAY™ Application is voluntary and data are only collected after physicians opt in.

~60min skin to skin with QDOT MICRO™ Catheter is possible¹



Ablation Phase: time from first until last RF application, Skin Time: time from femoral puncture until removal of last sheath from the patient; first catheter in/last catheter out, FPI: first pass isolation, NTags: number of ablation tags used to isolate the veins, RF time: radiofrequency time used.

During LMR experience with QDOT MICRO™ Catheter ~40% (29/75) of users perform QDOT MICRO™ Catheter cases in less than 60min skin to skin and are therefore part of the EMEA Benchmark.

Additional analysis showed that **long ablation phase** with QDOT MICRO™ Catheter are strongly correlated **with higher number of Visitags** ($R=0,48$), thus working on number of Visitags (aim for ~60 as reported in the graph by the NTags data) will most likely decrease ablation phase time

Looking at the number of QDOT MICRO™ Catheter cases performed by user per week, it was found that **users with >3 cases/week had a shorter skin to skin time** compared to users performing <3 cases/week (reduction of ~20%). Therefore performing at least 3 QDOT MICRO™ Catheter cases per week might help to reduce skin to skin time.

Comparison of median skin time between intensive and moderate QDOT users

Number of intensive users : 3; Number of moderate users : 13

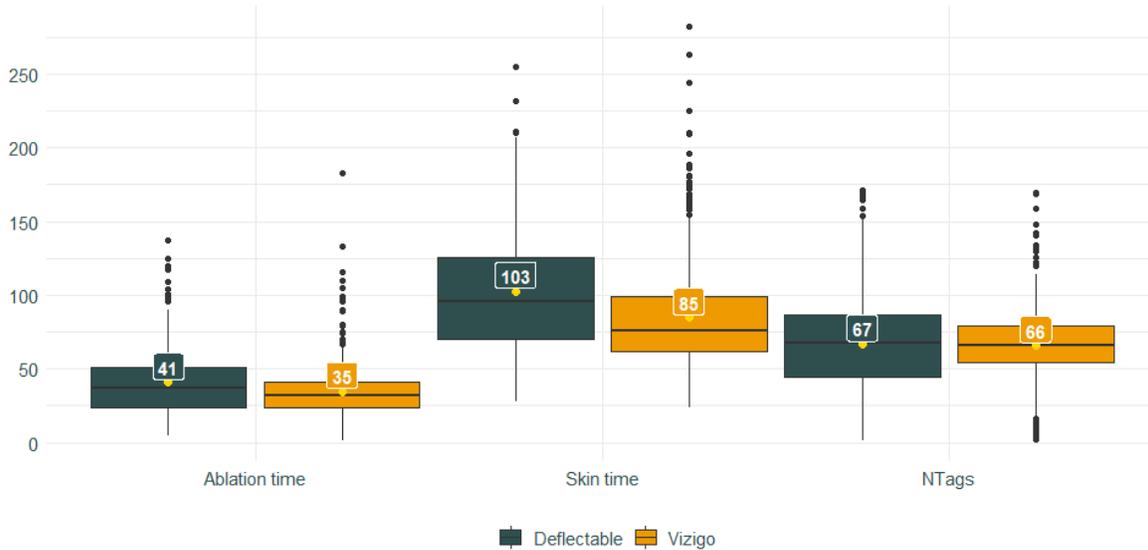


A surgeon is considered as an 'intensive' QDOT user if he performed on average 3 cases per week (i.e. 12 cases per month), during the first two months of use.

WHY TO USE CARTO VIZIGO™ Bi-directional Guiding Sheath WITH QDOT MICRO™?

PAF INDICATORS BY SHEATH TYPE

N cases deflectable: 286; N cases Vizigo: 606



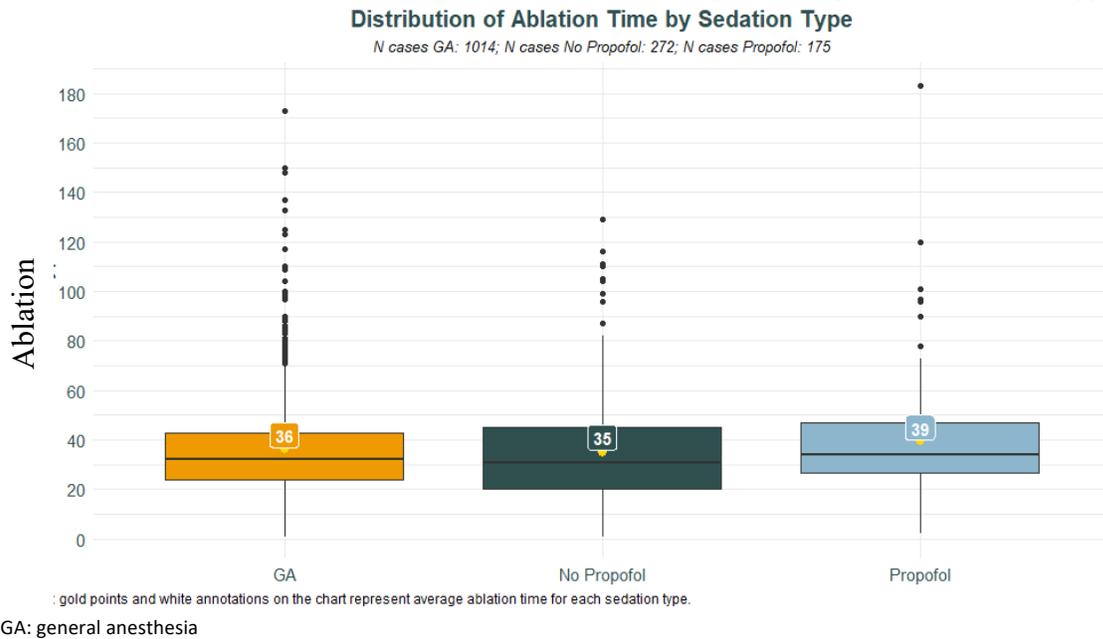
Ablation Phase: time from first until last RF application, Skin Time: time from femoral puncture until removal of last sheath from the patient; first catheter in/last catheter out, NTags: number of ablation tags used to isolate the veins.

CARTO VIZIGO™ Bi-directional Guiding Sheath shows **reduced time and variability of the Ablation and Skin-to-Skin** phases when compared with other (non-visualized) deflectable sheaths.

CARTO VIZIGO™ Bi-directional Guiding Sheath shows **less variability in number of Visitags (NTags) per case = better stability?**

This product can only be used by healthcare professionals in EMEA.

Similar Ablation Phase times can be achieved independently of the sedation type



Reference:

1. Tilz, R. et al (2021). Very high-power short-duration temperature-controlled ablation versus conventional power-controlled ablation for pulmonary vein isolation: The fast and furious - AF study. *International journal of cardiology. Heart & vasculature*, 35, 100847.

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For product details such as indications, contraindications, warnings and precautions please consult the IFU.

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